Washington State Department of Health

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

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Specimen Submission to State Public Health Laboratories

by Donna Duffy, DOH/PHL

Notifiable Conditions: According to the Washington Administrative Code, **laboratories are required to report notifiable conditions to the local health jurisdiction (LHJ)** where the patient resides (**WAC 246-101-120)**. It is important that laboratory test results are reported to LHJs in a timely manner so that cases can be investigated. Delays in notifying LHJs of communicable disease cases can result in serious public health consequences. For a listing of conditions that are **immediately notifiable** for laboratories, visit the DOH Notifiable Conditions website at http://www.doh.wa.gov/notify/other/labposter.pdf. To review the Washington Administrative Code, go to http://www.doh.wa.gov/notify/other/legal.htm#wac246-101-201.

What information should routinely be included with specimen submission? The Washington State Department of Health Public Health Laboratories (PHL) place a strong emphasis on providing timely results. For information regarding specimen submission requirements and to order PHL laboratory test requisitions/shipping containers, contact the PHL Mailroom at (206) 361-2865. An updated PHL Laboratory Users Manual is scheduled to be posted on the PHL website toward the end of the year: http://www.doh.wa.gov/EHSPHL/PHL/.

In order to ensure timely reporting, the PHL requests that laboratories fill out the laboratory test requisition form on each specimen submitted and include the following information:

- Patient name
- A second patient identifier (e.g., SS#, DOB, hospital#, middle initial) to prevent confusing specimens from patients with the same or similar names
- Complete patient address (*including **city, county** and **zip code***)
- Submitting laboratory name, return address and phone number
- Specimen type
- Agent being tested for
- Collection date
- Date of illness onset, if applicable
- Patient travel history, if applicable

The patient's name must be on each specimen tube and must match the name on the form.

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Inside This Issue

Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:
www.doh.wa.gov/lqa.htm

Anemia	Lipid Screening
ANA	Point-of-Care Testing
Bioterrorism Event Mgmt	PSA
Bleeding Disorders	Rash Illness
Chlamydia	Red Cell Transfusion
Diabetes	Renal Disease
Group A Strep Pharyngitis	STD
Hepatitis	Thyroid
HIV	Tuberculosis
Infectious Diarrhea	Urinalysis
Intestinal Parasites	Wellness

Bioterrorism Corner: Did You Know?

by Candace Bunch, DOH/PHL

BT Vaccines: Funding of $232 million has been approved to develop vaccines against smallpox, plague and tularemia. The monies will fund early-stage product development including dosage formulation, pilot batch production and initial clinical assessment. The smallpox awards support larger scale manufacturing of modified vaccine candidates. A highly attenuated strain of vaccinia virus which has lost about 10% of its genome and has limited ability to replicate has successfully and safely vaccinated over 120,000 people. It is known as the Modified Vaccinia Ankara vaccine or MVA. Acambis, Inc. is co-developing its version of the MVA vaccine with Baxter Healthcare. Bavarian Nordic Research Institute in Denmark is currently developing a clinical trial to assess the safety and preliminary immunogenicity of their MVA.

Oral Anthrax Vaccine: The Navy will conduct the first human clinical trials of an oral anthrax vaccine developed by Fraunhofer USA (Newark, NJ). This oral vaccine is derived from plants and is specifically designed to be safer than the current injectable version. The oral vaccine will be easier to administer and to stockpile. The first trial with about 30 volunteers will begin in mid-2005.

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LQA home page: http://www.doh.wa.gov/lqa.htm
PHL home page:
http://www.doh.wa.gov/EHSPHL/PHL/default.htm

DNA-based Anthrax Vaccine: Vical, Inc. (San Diego, CA) is developing a novel cationic lipid-formulated plasmid DNA anthrax vaccine. The vaccine was proven to provide complete protection of rabbits against an aerosolized inhalation spore challenge more than seven months after vaccination. The DNA encodes the detoxified forms of both the Protective Antigen (PA) and Lethal Factor (LF) anthrax proteins, which in their natural forms combine to form lethal toxin. Significant levels of anti-PA, anti-LF and other neutralizing antibodies were observed in the rabbit study. Post-challenge immune response data suggest that these same antibodies may even inhibit the germination of anthrax spores. The vaccine is now being tested for safety and immune responses in a Phase 1 clinical trial in healthy human volunteers through the U.S. National Institute of Allergy and Infectious Diseases.

The 20-Minute BT Assay: Weihong Tan et al, at the University of Florida, have created bioconjugated nanoparticles that can detect specific bacteria in food within minutes. By utilizing a silica structure to bind a specific antibody to thousands of fluorescent dye molecules, they are able to amplify the antibody-antigen binding signal. Enhancing the fluorescent signal eliminates the need to wait for bacterial growth, allowing for even a single bacterium to be detected within minutes. This assay could have a huge impact in the food industry. The team is currently adapting the assay to detect multiple bacteria simultaneously.

The Bot Tox Test: Edwin Chapman, a physiologist at the University of Wisconsin in Madison, has developed a rapid botulinum toxin test that could replace the current clinical assay that utilizes mice. His group determined that the toxin targets three key proteins that are essential for mediating the release of chemical signals from neurons. And this governs how messages are sent from the brain to muscles. The testing method requires the attachment of two proteins derived from a green fluorescent protein, to the plasma-membrane proteins that are targeted and cleaved by the toxin. When the proteins are intact, a fluorescent signal can be detected. When the proteins are cleaved, the signal is abolished. The tests are capable of detecting all seven variants of the poison. With this information they can now begin rapid screening for new drug compounds that can inhibit the

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Specimen Submission, continued from page 1

Complete patient address information with specimen submission is necessary to enable the PHL to send results immediately to the appropriate LHJ. Without patient residence information, transfer of testing results to the proper LHJ can be delayed, resulting in delays in investigation and public health interventions.

In some instances, the submitting laboratory is unable to provide the needed information because it was not provided this information by health care providers and others submitting specimens. In these cases, laboratories should immediately contact the submitter to obtain patient's county of residence information. In addition, laboratories are encouraged to educate their clients about the importance of supplying this information on a routine basis.

Other reminders: It's important to follow correct specimen collection, storage, packaging, and shipping procedures when sending a specimen to the PHL. Specimens that have been mishandled or stored at improper temperature may yield inconclusive results. Be aware that some specimens require prior notification and approval in order to be tested. For questions on these and other issues, contact the PHL mailroom (206-361-2865) or the Virology Unit (206-361-2874). Every six months, the PHL offers training on specimen collection, storage, shipping and other laboratory-related subjects. Contact Shelley Lankford (206-361-2810) for a schedule of offerings.

PHL phone system change: Phone numbers are anticipated to change with the installation of the new PHL phone system, which is scheduled for November to early December of 2004. Look for information in the next issue of *Elaborations*. The toll-free PHL phone number will remain the same (877-539-4344).

Bioterrorism Corner: Did You Know? continued from page 2

toxin at its point of action. The researchers also are using the technique, which is sensitive to the picomolar level, to test for the presence of the toxin in substances such as milk.

Close to Home

The Pacific Northwest National Laboratory (PNNL) in Richland, WA has received a five-year $10.3 million biodefense contract from the National Institute of Allergies and Infectious Agents to study potential agents of bioterrorism, such as *Salmonella typhimurium* (food poisoning), *Salmonella typhi* (Typhoid Fever), and monkeypox virus (similar to the smallpox virus). By analyzing the interaction between these pathogens' microbial proteins and the host cells, effective treatments can be developed for use during an outbreak. Scientists at PNNL will use proteomics instruments and unique approaches to combine the high-resolution separation of proteins with their identification. The mass spectrometers were developed at the W.R. Wiley Environmental Molecular Science Laboratory right on the PNNL campus. Scientists at the Oregon Health & Science University (Portland) have been able to knock out key genes that regulate the degree of pathogenic activity in organisms. They will prepare the organisms for the PNNL analysis and will assist in analyzing the data generated there.

BD Vacutainer Technical Bulletin

On September 23, 2004, BD Diagnostics issued a technical bulletin regarding interferences to certain immunoassay test procedures when using the SST glass and Plus plastic blood collection tubes. For more information about this technical bulletin go to the BD website (http://www.bd.com) and do a search for "technical bulletins from September 23, 2004" or contact your BD representative. If your reference laboratory performs immunoassay testing for your facility, contact your reference laboratory for direction if you have not already received information from them.

Calendar of Events

PHL Training Classes:
(http://www.doh.wa.gov/EHSPHL/PHL/train.htm)

Parasitology Part II: Protozoans
January 12 & 13, 2005 Shoreline

Handling & Shipping of Biohazardous Materials
January 20, 2005 Shoreline

2005 WSSCLS/NWSSAMT Spring Meeting
April 28-30, 2005 Spokane

Northwest Medical Laboratory Symposium
October 26-29, 2005 Seattle

12th Annual Clinical Laboratory Conference
November, 2005 Seattle

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

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